

HM Coroner Mr. Andrew Cox
Coroner for Cornwall & the Isles of Scilly
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BY EMAIL AND POST

12 April 2021

Care Quality Commission (CQC)

Our Reference: [REDACTED]

Dear HM Senior Coroner Cox

Prevention of future deaths report following the Inquest into the death of Katie Emma Corrigan.

Thank you for your Regulation 28 report to prevent future deaths issued following the inquest into the sad death of Katie Emma Corrigan.

Prevention of Future Deaths Report

Under Section 6 of your report entitled "Action that should be taken" you noted as follows in particular:

- *The absence of a requirement for doctors in the private sector to contact a registered GP prior to dispensing opiate medication to a patient leaves the system open to abuse.*
- *One of the on-line pharmacies identified above openly advertises itself as offering a 'discreet' service which I interpret as a willingness to circumvent the existing, inadequate controls. I do not know but am bound to wonder if there is a professional or financial relationship between the prescribing doctor and dispensing pharmacist and, if so, whether this is considered ethical or meeting current professional standards?*
- *The Alert system appears cumbersome and ineffective.*
- *All online prescribing services accessible by patients in England should be regulated by the CQC, regardless of which professional groups are doing*

the prescribing, regardless of where in the world those prescribers are registered, and regardless of where in the world the provider's head office is. This would require a change in regulation by the Department of Health & Social Care.

CQC inspection of online provider services

As you are already aware the Care Quality Commission (CQC) is the independent regulator for health and social care in England. CQC's purpose is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve. CQC's functions are to register health and adult social care service providers in England; to monitor, inspect and rate services; and to take action to protect people where appropriate using its powers under Health and Social Care Act 2008 and associated regulations.

As part of an online provider inspection CQC routinely checks the management of medicines, prescriptions, consent and sharing information with a patient's other health care providers. CQC recognises that a provider's management of medicines and prescriptions in this way can be restricted where patients have not provided consent to share information and/or where a patient has used alternative identification.

CQC has published guidance for providers¹. The guidance describes the expectations of providers to ensure a patient's GP is informed of prescribed medications from their service. We also expect that should the patient decline to consent for the sharing of such information to take place, the prescriber should consider whether it is still safe to continue and accept the full responsibility for their actions and act in line with GMC prescribing guidance.

All providers must comply with the regulations as set out in The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (RAR 2014). The regulations that would be most relevant to any reviews around online providers would be:

- Regulation 9 (Person-Centred Care);
- Regulation 11 (Need for Consent);
- Regulation 12 (Safe Care and Treatment including the safe use of medicines);
- Regulation 13 (Safeguarding service users from abuse and improper treatment); and
- Regulation 17 (Good Governance)

¹ [How CQC monitors, inspects and regulates ONLINE PRIMARY CARE](#), April 2019

For all health and social care providers, CQC would look at the regulations outlined above and determine whether there is evidence of compliance under each of the Key Lines of Enquiry (KLOE) relative to the provider type.

A registered provider's compliance with the regulations will be assessed at inspection. As part of a CQC comprehensive inspection the online provider will be inspected against five key questions, whether a service is safe, effective, caring, responsive and well led. Each of the five key questions are broken down into a further set of questions, the key lines of enquiry (KLOEs). When CQC inspects, these are used to help CQC decide what the inspection needs to focus on. For example, the inspection team will look at the management of medicines and prescriptions, consent, identity checks and sharing information with a patients' other health care providers. As part of the consideration as to whether a service is safe, effective, caring, responsive or well led, CQC will consider how governance systems, processes and practices keep people safe, how these are monitored and improved and whether staff receive effective training in safety systems, processes and practices.

Online Provider Regulatory Framework Concerns:

CQC regulates providers of online primary care services based in England where they are delivering a regulated activity by an online means. This includes providers prescribing medicines in response to online forms. Providers of controlled drugs based in England must comply with legislation, which is enforced by CQC, as well as other healthcare regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA) and the General Pharmaceutical Council (GPhC). In addition, all healthcare professionals are subject to their respective codes of professional conduct and these are enforced by, for example, the GPhC for pharmacists or the General Medical Council (GMC) for doctors.

Through our regulation of independent online primary medical services, CQC has identified gaps in the regulatory framework for online providers. We share HM Coroner's concerns that members of the public may be able to source medicines with the potential for harm from providers who structure their business in such a way as to be outside the scope of registration with the CQC or the GPhC. We are also aware that our regulatory partners, including MHRA and the GPhC, share our concerns about the lack of regulatory oversight in this area.

In the last few years, CQC has extensively engaged with members of a UK-wide cross-regulatory forum to improve oversight of these providers. Although CQC has taken enforcement action against online providers we also identify that our ability to regulate in this space in certain circumstances where we see unsafe or criminal practice is restricted by legislative barriers and limitations in this area. CQC recognises the regulatory framework in this area needs to be updated to address emerging risks and to ensure independent online prescribers adhere to safe practice.

Since January 2021 CQC has been in discussions with, and submitted, proposals for legislative changes to the Department of Health and Social Care (DHSC), to improve CQC's ability to take action against independent providers of online primary care services that are putting people's lives at risk. In particular, we are looking to address safety gaps in the following areas:

- over prescribing of opioids and other medicines online;
- prescribing online without knowledge of a patient's history or access to patient records;
- the type and quantities of medicines that can be prescribed by independent providers online;
- the lack of measures and checks in place when medicines are dispensed in England, following a prescription from outside England; and
- limited jurisdictional ability for UK regulators to take action in response to harmful prescribing by providers or registered persons based outside the UK.

DHSC are currently working with CQC to look at how regulation can be best updated to address the areas outlined above, as well as to address current and emerging threats to the health, safety and wellbeing of service users from online providers. This includes looking at what issues can be addressed through legislative change (primary and secondary). CQC is also looking to work more closely with our partners, other regulators (including MHRA and GPhC) and other government organisations to explore other opportunities for taking this work forward.

CQC Regulatory Action:

CQC has inspected each of the registered online providers that you identified from the inquest into Ms Corrigan's death that Ms Corrigan may have used. At each inspection, management processes for prescribing medications were reviewed and if concerns were identified we took regulatory action against the provider or the inspection report shared details of the areas needing improvement.

We have identified that two of the online providers whose details you shared are not currently registered to carry on regulated activities. You may be aware that under section 10 Health and Social Care Act 2008 it is an offence for persons to carry on regulated activities without being registered with the CQC to do so. We are currently following our processes to investigate those providers you shared with us, to ensure these do not remain as unregistered providers and we may take enforcement action as appropriate and necessary upon conclusion of our enquiries.

Where CQC identifies that regulations are not being met, we use our enforcement powers to require improvements to be made. We continue to do this and will share key learning and practice points from the inquest into the death of Katie Corrigan.

We hope that this response addresses your concerns. Should you require any further information then please do not hesitate to get in touch.

Yours sincerely

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.A solid black rectangular box redacting the name of the signatory.

Head of Inspection- PMS South East and South West.